

AMENDED IN ASSEMBLY SEPTEMBER 3, 2013

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AMENDED IN SENATE MAY 28, 2013

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AMENDED IN SENATE MAY 1, 2013

SENATE BILL

No. 809

Introduced by Senators DeSaulnier and Steinberg
(Coauthors: Senators Hancock, Lieu, Pavley, and Price)
(Coauthor: Assembly Member Blumenfield)

February 22, 2013

An act to add Sections 208, 209, and 2196.8 to the Business and Professions Code, and to amend Sections 11164.1, 11165, and 11165.1 of, and to add Section ~~11165.4~~ 11165.5 to, the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 809, as amended, DeSaulnier. Controlled substances: reporting.

(1) Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

Existing law requires dispensing pharmacies and clinics to report, on a weekly basis, specified information for each prescription of Schedule II, Schedule III, or Schedule IV controlled substances, to the department, as specified.

This bill would establish the CURES Fund within the State Treasury to receive funds to be allocated, upon appropriation by the Legislature, to the Department of Justice for the purposes of funding CURES, and would make related findings and declarations.

This bill ~~would~~ *would, beginning April 1, 2014*, require an annual fee of \$6 to be assessed on specified licensees, including licensees authorized to prescribe, order, administer, furnish, or dispense controlled substances, and require the regulating agency of each of those licensees to bill and collect that fee at the time of license renewal. The bill would authorize the Department of Consumer Affairs to reduce, by regulation, that fee to the reasonable cost of operating and maintaining CURES for the purpose of regulating those licensees, if the reasonable regulatory cost is less than \$6 per licensee. The bill would require the proceeds of the fee to be deposited into the CURES Fund for the support of CURES, as specified. The bill would also permit specified insurers, health care service plans, qualified manufacturers, and other donors to voluntarily contribute to the CURES Fund, as described.

(2) Existing law requires the Medical Board of California to periodically develop and disseminate information and educational materials regarding various subjects, including pain management techniques, to each licensed physician and surgeon and to each general acute care hospital in California.

This bill would additionally require the board to periodically develop and disseminate to each licensed physician and surgeon and to each general acute care hospital in California information and educational materials relating to the assessment of a patient's risk of abusing or diverting controlled substances and information relating to CURES.

(3) Existing law permits a licensed health care practitioner, as specified, or a pharmacist to apply to the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient under his or her care. Existing law also authorizes the Department of Justice to provide the history of controlled substances dispensed to an individual to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

This bill would require, by January 1, 2016, or upon receipt of a federal Drug Enforcement Administration registration, whichever occurs later, health care practitioners authorized to prescribe, order, administer, furnish, or dispense controlled substances, as specified, and pharmacists to apply to the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient under their care. The bill would require the Department of Justice, in conjunction with the Department of Consumer Affairs and certain licensing boards, to, among other things, develop a streamlined application and approval process to provide access to the CURES database for licensed health care practitioners and pharmacists. The bill would make other related and conforming changes.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. The Legislature finds and declares all of the
- 2 following:
- 3 (a) The Controlled Substance Utilization Review and Evaluation
- 4 System (CURES) is a valuable preventive, investigative, and
- 5 educational tool for health care providers, regulatory agencies,
- 6 educational researchers, and law enforcement. Recent budget cuts
- 7 to the Attorney General's Division of Law Enforcement have
- 8 resulted in insufficient funding to support CURES and its
- 9 Prescription Drug Monitoring Program (PDMP). The CURES
- 10 PDMP is necessary to ensure health care professionals have the
- 11 necessary data to make informed treatment decisions and to allow
- 12 law enforcement to investigate diversion of prescription drugs.
- 13 Without a dedicated funding source, the CURES PDMP is not
- 14 sustainable.
- 15 (b) Each year CURES responds to more than 800,000 requests
- 16 from practitioners and pharmacists regarding all of the following:
- 17 (1) Helping identify and deter drug abuse and diversion of
- 18 prescription drugs through accurate and rapid tracking of Schedule
- 19 II, Schedule III, and Schedule IV controlled substances.
- 20 (2) Helping practitioners make prescribing decisions.
- 21 (3) Helping reduce misuse, abuse, and trafficking of those drugs.
- 22 (c) Schedule II, Schedule III, and Schedule IV controlled
- 23 substances have had deleterious effects on private and public

1 interests, including the misuse, abuse, and trafficking in dangerous
2 prescription medications resulting in injury and death. It is the
3 intent of the Legislature to work with stakeholders to fully fund
4 the operation of CURES which seeks to mitigate those deleterious
5 effects and serve as a tool for ensuring safe patient care, and which
6 has proven to be a cost-effective tool to help reduce the misuse,
7 abuse, and trafficking of those drugs.

8 (d) The following goals are critical to increase the effectiveness
9 and functionality of CURES:

10 (1) Upgrading the CURES PDMP so that it is capable of
11 accepting real-time updates and is accessible in real-time, 24 hours
12 a day, seven days a week.

13 (2) Upgrading the CURES PDMP in California so that it is
14 capable of operating in conjunction with all national prescription
15 drug monitoring programs.

16 (3) Providing subscribers to prescription drug monitoring
17 programs access to information relating to controlled substances
18 dispensed in California, including those dispensed through the
19 United States Department of Veterans Affairs, the Indian Health
20 Service, the Department of Defense, and any other entity with
21 authority to dispense controlled substances in California.

22 (4) Upgrading the CURES PDMP so that it is capable of
23 accepting the reporting of electronic prescription data, thereby
24 enabling more reliable, complete, and timely prescription
25 monitoring.

26 SEC. 2. Section 208 is added to the Business and Professions
27 Code, to read:

28 208. (a) ~~A~~*Beginning April 1, 2014, a* CURES fee of six dollars
29 (\$6) shall be assessed annually on each of the licensees specified
30 in subdivision (b) to pay the reasonable costs associated with
31 operating and maintaining CURES for the purpose of regulating
32 those licensees. The fee assessed pursuant to this subdivision shall
33 be billed and collected by the regulating agency of each licensee
34 at the time of the licensee's license renewal. If the reasonable
35 regulatory cost of operating and maintaining CURES is less than
36 six dollars (\$6) per licensee, the Department of Consumer Affairs
37 may, by regulation, reduce the fee established by this section to
38 the reasonable regulatory cost.

39 (b) (1) Licensees authorized pursuant to Section 11150 of the
40 Health and Safety Code to prescribe, order, administer, furnish,

1 or dispense Schedule II, Schedule III, or Schedule IV controlled
2 substances or pharmacists licensed pursuant to Chapter 9
3 (commencing with Section 4000) of Division 2.

4 (2) Wholesalers and nonresident wholesalers of dangerous drugs
5 licensed pursuant to Article 11 (commencing with Section 4160)
6 of Chapter 9 of Division 2.

7 (3) Nongovernmental clinics licensed pursuant to Article 13
8 (commencing with Section 4180) and Article 14 (commencing
9 with Section 4190) of Chapter 9 of Division 2.

10 (4) Nongovernmental pharmacies licensed pursuant to Article
11 7 (commencing with Section 4110) of Chapter 9 of Division 2.

12 (c) The funds collected pursuant to subdivision (a) shall be
13 deposited in the CURES Fund, which is hereby created within the
14 State Treasury. Moneys in the CURES Fund shall, upon
15 appropriation by the Legislature, be available to the Department
16 of Consumer Affairs to reimburse the Department of Justice for
17 costs to operate and maintain CURES for the purposes of regulating
18 the licensees specified in subdivision (b).

19 (d) The Department of Consumer Affairs shall contract with
20 the Department of Justice on behalf of the Medical Board of
21 California, the Dental Board of California, the California State
22 Board of Pharmacy, the Veterinary Medical Board, the Board of
23 Registered Nursing, the Physician Assistant Board of the Medical
24 Board of California, the Osteopathic Medical Board of California,
25 the Naturopathic Medicine Committee of the Osteopathic Medical
26 Board, the State Board of Optometry, and the California Board of
27 Podiatric Medicine to operate and maintain CURES for the
28 purposes of regulating the licensees specified in subdivision (b).

29 SEC. 3. Section 209 is added to the Business and Professions
30 Code, to read:

31 209. The Department of Justice, in conjunction with the
32 Department of Consumer Affairs and the boards and committees
33 identified in subdivision (d) of Section 208, shall do all of the
34 following:

35 (a) Identify and implement a streamlined application and
36 approval process to provide access to the CURES Prescription
37 Drug Monitoring Program (PDMP) database for licensed health
38 care practitioners eligible to ~~prescribe~~ *prescribe, order, administer,*
39 *furnish, or dispense* Schedule II, Schedule III, or Schedule IV
40 controlled substances and for pharmacists. Every reasonable effort

1 shall be made to implement a streamlined application and approval
2 process that a licensed health care practitioner or pharmacist can
3 complete at the time that he or she is applying for licensure or
4 renewing his or her license.

5 (b) Identify necessary procedures to enable licensed health care
6 practitioners and pharmacists with access to the CURES PDMP
7 to delegate their authority to order reports from the CURES PDMP.

8 (c) Develop a procedure to enable health care practitioners who
9 do not have a federal Drug Enforcement Administration (DEA)
10 number to opt out of applying for access to the CURES PDMP.

11 SEC. 4. Section 2196.8 is added to the Business and Professions
12 Code, to read:

13 2196.8. The board shall periodically develop and disseminate
14 information and educational material regarding assessing a patient's
15 risk of abusing or diverting controlled substances and information
16 relating to the Controlled Substance Utilization Review and
17 Evaluation System (CURES), described in Section 11165 of the
18 Health and Safety Code, to each licensed physician and surgeon
19 and to each general acute care hospital in this state. The board
20 shall consult with the State Department of Public Health, the boards
21 and committees specified in subdivision (d) of Section 208, and
22 the Department of Justice in developing the materials to be
23 distributed pursuant to this section.

24 SEC. 5. Section 11164.1 of the Health and Safety Code is
25 amended to read:

26 11164.1. (a) (1) Notwithstanding any other provision of law,
27 a prescription for a controlled substance issued by a prescriber in
28 another state for delivery to a patient in another state may be
29 dispensed by a California pharmacy, if the prescription conforms
30 with the requirements for controlled substance prescriptions in the
31 state in which the controlled substance was prescribed.

32 ~~(b)~~

33 (2) All prescriptions for Schedule II, Schedule III, and Schedule
34 IV controlled substances dispensed pursuant to this subdivision
35 shall be reported by the dispensing pharmacy to the Department
36 of Justice in the manner prescribed by subdivision (d) of Section
37 11165.

38 (b) *Pharmacies may dispense prescriptions for Schedule III,*
39 *Schedule IV, and Schedule V controlled substances from*
40 *out-of-state prescribers pursuant to Section 4005 of the Business*

1 *and Professions Code and Section 1717 of Title 16 of the California*
2 *Code of Regulations.*

3 SEC. 6. Section 11165 of the Health and Safety Code is
4 amended to read:

5 11165. (a) To assist health care practitioners in their efforts
6 to ensure appropriate prescribing, ordering, administering,
7 furnishing, and dispensing of controlled substances, law
8 enforcement and regulatory agencies in their efforts to control the
9 diversion and resultant abuse of Schedule II, Schedule III, and
10 Schedule IV controlled substances, and for statistical analysis,
11 education, and research, the Department of Justice shall, contingent
12 upon the availability of adequate funds in the CURES Fund,
13 maintain the Controlled Substance Utilization Review and
14 Evaluation System (CURES) for the electronic monitoring of, and
15 Internet access to information regarding, the prescribing and
16 dispensing of Schedule II, Schedule III, and Schedule IV controlled
17 substances by all practitioners authorized to prescribe, order,
18 administer, furnish, or dispense these controlled substances.

19 (b) The Department of Justice may seek and use grant funds to
20 pay the costs incurred by the operation and maintenance of
21 CURES. The department shall annually report to the Legislature
22 and make available to the public the amount and source of funds
23 it receives for support of CURES.

24 (c) (1) The operation of CURES shall comply with all
25 applicable federal and state privacy and security laws and
26 regulations.

27 (2) CURES shall operate under existing provisions of law to
28 safeguard the privacy and confidentiality of patients. Data obtained
29 from CURES shall only be provided to appropriate state, local,
30 and federal public agencies for disciplinary, civil, or criminal
31 purposes and to other agencies or entities, as determined by the
32 Department of Justice, for the purpose of educating practitioners
33 and others in lieu of disciplinary, civil, or criminal actions. Data
34 may be provided to public or private entities, as approved by the
35 Department of Justice, for educational, peer review, statistical, or
36 research purposes, provided that patient information, including
37 any information that may identify the patient, is not compromised.
38 Further, data disclosed to any individual or agency as described
39 in this subdivision shall not be disclosed, sold, or transferred to
40 any third party. The Department of Justice shall establish policies,

1 procedures, and regulations regarding the use, access, evaluation,
2 management, implementation, operation, storage, disclosure, and
3 security of the information within CURES, consistent with this
4 subdivision.

5 (d) For each prescription for a Schedule II, Schedule III, or
6 Schedule IV controlled substance, as defined in the controlled
7 substances schedules in federal law and regulations, specifically
8 Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21
9 of the Code of Federal Regulations, the dispensing pharmacy,
10 clinic, or other dispenser shall report the following information to
11 the Department of Justice as soon as reasonably possible, but not
12 more than seven days after the date a controlled substance is
13 dispensed, in a format specified by the Department of Justice:

14 (1) Full name, address, ~~and~~ *and, if available*, telephone number
15 of the ultimate user or research subject, or contact information as
16 determined by the Secretary of the United States Department of
17 Health and Human Services, and the gender, and date of birth of
18 the ultimate user.

19 (2) The prescriber's category of licensure, *license number*,
20 national provider identifier (NPI) number, *if applicable*, the federal
21 controlled substance registration number, and the state medical
22 license number of any prescriber using the federal controlled
23 substance registration number of a government-exempt facility.

24 (3) Pharmacy prescription number, license number, NPI number,
25 and federal controlled substance registration number.

26 (4) National Drug Code (NDC) number of the controlled
27 substance dispensed.

28 (5) Quantity of the controlled substance dispensed.

29 (6) International Statistical Classification of Diseases, 9th
30 revision (ICD-9) or 10th revision (ICD-10) Code, if available.

31 (7) Number of refills ordered.

32 (8) Whether the drug was dispensed as a refill of a prescription
33 or as a first-time request.

34 (9) Date of origin of the prescription.

35 (10) Date of dispensing of the prescription.

36 (e) The Department of Justice may invite stakeholders to assist,
37 advise, and make recommendations on the establishment of rules
38 and regulations necessary to ensure the proper administration and
39 enforcement of the CURES database. All prescriber and dispenser
40 invitees shall be licensed by one of the boards or committees

1 identified in subdivision (d) of Section 208 of the Business and
2 Professions Code, in active practice in California, and a regular
3 user of CURES.

4 (f) The Department of Justice shall, prior to upgrading CURES,
5 consult with prescribers licensed by one of the boards or
6 committees identified in subdivision (d) of Section 208 of the
7 Business and Professions Code, one or more of the boards or
8 committees identified in subdivision (d) of Section 208 of the
9 Business and Professions Code, and any other stakeholder
10 identified by the department, for the purpose of identifying
11 desirable capabilities and upgrades to the CURES Prescription
12 Drug Monitoring Program (PDMP).

13 (g) The Department of Justice may establish a process to educate
14 authorized subscribers of the CURES PDMP on how to access and
15 use the CURES PDMP.

16 SEC. 7. Section 11165.1 of the Health and Safety Code is
17 amended to read:

18 11165.1. (a) (1) (A) (i) A health care practitioner authorized
19 to prescribe, order, administer, furnish, or dispense Schedule II,
20 Schedule III, or Schedule IV controlled substances pursuant to
21 Section 11150 ~~or a pharmacist~~ shall, before January 1, 2016, or
22 upon receipt of a federal Drug Enforcement Administration (DEA)
23 registration, whichever occurs later, submit an application
24 developed by the Department of Justice to obtain approval to access
25 information online regarding the controlled substance history of
26 a patient that is stored on the Internet and maintained within the
27 Department of Justice, and, upon approval, the department shall
28 release to that practitioner ~~or pharmacist~~ the electronic history of
29 controlled substances dispensed to an individual under his or her
30 care based on data contained in the CURES Prescription Drug
31 Monitoring Program (PDMP).

32 (ii) *A pharmacist shall, before January 1, 2016, or upon*
33 *licensure, whichever occurs later, submit an application developed*
34 *by the Department of Justice to obtain approval to access*
35 *information online regarding the controlled substance history of*
36 *a patient that is stored on the Internet and maintained within the*
37 *Department of Justice, and, upon approval, the department shall*
38 *release to that pharmacist the electronic history of controlled*
39 *substances dispensed to an individual under his or her care based*
40 *on data contained in the CURES PDMP.*

1 ~~(A)~~

2 (B) An application may be denied, or a subscriber may be
3 suspended, for reasons which include, but are not limited to, the
4 following:

5 (i) Materially falsifying an application for a subscriber.

6 (ii) Failure to maintain effective controls for access to the patient
7 activity report.

8 (iii) Suspended or revoked federal DEA registration.

9 (iv) Any subscriber who is arrested for a violation of law
10 governing controlled substances or any other law for which the
11 possession or use of a controlled substance is an element of the
12 crime.

13 (v) Any subscriber accessing information for any other reason
14 than caring for his or her patients.

15 ~~(B)~~

16 (C) Any authorized subscriber shall notify the Department of
17 Justice within 30 days of any changes to the subscriber account.

18 (2) A health care practitioner authorized to ~~prescribe~~ *prescribe*,
19 *order, administer, furnish, or dispense* Schedule II, Schedule III,
20 or Schedule IV controlled substances pursuant to Section 11150
21 or a pharmacist shall be deemed to have complied with paragraph
22 (1) if the licensed health care practitioner or pharmacist has been
23 approved to access the CURES database through the process
24 developed pursuant to subdivision (a) of Section 209 of the
25 Business and Professions Code.

26 (b) Any request for, or release of, a controlled substance history
27 pursuant to this section shall be made in accordance with guidelines
28 developed by the Department of Justice.

29 (c) In order to prevent the inappropriate, improper, or illegal
30 use of Schedule II, Schedule III, or Schedule IV controlled
31 substances, the Department of Justice may initiate the referral of
32 the history of controlled substances dispensed to an individual
33 based on data contained in CURES to licensed health care
34 practitioners, pharmacists, or both, providing care or services to
35 the individual.

36 (d) The history of controlled substances dispensed to an
37 individual based on data contained in CURES that is received by
38 a practitioner or pharmacist from the Department of Justice
39 pursuant to this section shall be considered medical information
40 subject to the provisions of the Confidentiality of Medical

1 Information Act contained in Part 2.6 (commencing with Section
2 56) of Division 1 of the Civil Code.

3 (e) Information concerning a patient's controlled substance
4 history provided to a prescriber or pharmacist pursuant to this
5 section shall include prescriptions for controlled substances listed
6 in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code
7 of Federal Regulations.

8 SEC. 8. Section ~~11165.4~~ *11165.5* is added to the Health and
9 Safety Code, to read:

10 ~~11165.4.~~

11 *11165.5.* (a) The Department of Justice may seek voluntarily
12 contributed private funds from insurers, health care service plans,
13 qualified manufacturers, and other donors for the purpose of
14 supporting CURES. Insurers, health care service plans, qualified
15 manufacturers, and other donors may contribute by submitting
16 their payment to the Controller for deposit into the CURES Fund
17 established pursuant to subdivision (c) of Section 208 of the
18 Business and Professions Code. The department shall make
19 information about the amount and the source of all private funds
20 it receives for support of CURES available to the public.
21 Contributions to the CURES Fund pursuant to this subdivision
22 shall be nondeductible for state tax purposes.

23 (b) For purposes of this section, the following definitions apply:

24 (1) "Controlled substance" means a drug, substance, or
25 immediate precursor listed in any schedule in Section 11055,
26 11056, or 11057 of the Health and Safety Code.

27 (2) "Health care service plan" means an entity licensed pursuant
28 to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter
29 2.2 (commencing with Section 1340) of Division 2 of the Health
30 and Safety Code).

31 (3) "Insurer" means an admitted insurer writing health insurance,
32 as defined in Section 106 of the Insurance Code, and an admitted
33 insurer writing workers' compensation insurance, as defined in
34 Section 109 of the Insurance Code.

35 (4) "Qualified manufacturer" means a manufacturer of a
36 controlled substance, but does not mean a wholesaler or nonresident
37 wholesaler of dangerous drugs, regulated pursuant to Article 11
38 (commencing with Section 4160) of Chapter 9 of Division 2 of
39 the Business and Professions Code, a veterinary food-animal drug
40 retailer, regulated pursuant to Article 15 (commencing with Section

1 4196) of Chapter 9 of Division 2 of the Business and Professions
2 Code, or an individual regulated by the Medical Board of
3 California, the Dental Board of California, the California State
4 Board of Pharmacy, the Veterinary Medical Board, the Board of
5 Registered Nursing, the Physician Assistant Committee of the
6 Medical Board of California, the Osteopathic Medical Board of
7 California, the State Board of Optometry, or the California Board
8 of Podiatric Medicine.

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